Emerging Health Policy Research Conference 2013

Abstract Submission

Presenters Details

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Short Biography of presenter (maximum 50 words):

David Lim has research interests in health policy, translation research and primary health. He is a member of the Public Health Association of Australia Primary Health Care Special Interest Group with expertise in pharmaceutical intellectual property based on law, public health, and medical qualifications and experience.

Presentation Details

Presentation Title (up to 10 Words):

Interferon-free therapy for hepatitis C, how prepared is Australia for biosimilars?

Keywords: (up to 5 to assist organisers in streaming papers):

1. Pharmaceutical policy
2. International health
3. Health systems
4. Quality Use of Medicines
5. National Medicines Policy

Research Details (250 word limit)

Introduction/Background:

The Hepatitis C virus (HCV) affects some 150 million people worldwide. However, unlike hepatitis A and B there is no vaccination for HCV and approximately 75% of people exposed to HCV develop chronic hepatitis. In Australia, around 226,700 people live with chronic HCV infection costing the government approximately $252 million per year. Historically, the standard approved/licenced treatment for HCV is pegylated interferon with ribavirin. There are major drawbacks with interferon-based therapy including side effects, long duration of therapy, limited

access and affordability. Our previous survey of an at-risk population reported HCV treatment coverage of only 5%.
Since April 2013, a new class of interferon-free treatments for chronic HCV is subsidised under the Pharmaceutical Benefits Scheme: boceprevir and telaprevir - estimated to cost the Australian Government in excess of $220 million over five years. Other biologic interferon-free therapeutic agents are scheduled to enter the Australian market. Use of small molecule generic pharmaceuticals has been advocated as a means of public cost savings. However, with the new biologic agents, generics (biosimilars) may not be feasible or straightforward, due to long patent life; marketing exclusivity; and regulatory complexity for these newer products.

Research Question:
How prepared is Australia for the regulation of biosimilars?

Methodology:
Exploratory case-study analysis of the regulatory framework for biosimilars in Australia. The case studied was the introduction of biosimilar-epoetin in 2006.

Findings:
Our current pharmaceutical regulatory framework is grounded in small molecule generics rather than biosimilars of innovator biologic therapies or vaccines. When biosimilar-epoetins entered the market, misapprehension of the nature of small molecule generics vs. biosimilars resulted in significant mortality and morbidity. Australia's Therapeutic Goods Administration looks to the European Medicines Agency for guidance on regulating biosimilars; however, this contradicts IP Australia's position, which advocates identical approaches to both biosimilars and small molecule generics. Australia's pharmaceutical regulation is influenced by economic pressure from its major trading partners.

Policy Implications:
Australia requires a consistent approach to the regulation of biosimilars, underpinned by the National Medicines Policy (2000): equity of access, safety and quality of pharmaceutical, whilst fostering innovation in Australia's pharmaceutical industry.